REMARKS

Status of Claims

Claims are amended as indicated in preceding list of claims. Claims 1-7 and 10 – 13, 15 and 20 - 24 are pending. Claim 8, 14, 16 – 19 were previously cancelled. Claims 20 – 24 are new. Note there is no mention of pending claim 15 as being rejected in the office action of 12/12/2007.

Claim Objections

Claim 3 is amended to clarify that the orifices are directed towards each other but only at angles where their longitudinal axes would intersect at acute angles. The claim would thus restrict the angles of the orifices to less than those where the orifices would be directed towards each other as this would require in the amended claim an intersection at 180 degrees.

Claim Rejections – 35 USC § 102

Claim 1 has been rejected under 35 USC 102(b) as being anticipated by Argraves, US 6,298,850 B1. Claim 1 has been amended in this response, but only to replace "said hollow main body portion" with "said hollow tubular member" since there was no precedence for the "hollow main body portion". Otherwise all elements of currently amended claim 1 are the same as the previous version. In general, the instant invention is directed at a three dimensional geometry for the cannula such that the placement of the cannula on the patient's face and direction of the orifice is maintained without a requirement for tension to be placed upon the cannula. This enables the use of the more flexible tubing for support tubing. Argraves uses an elastic cord to maintain tension and a nosepiece geometry to relieve pressure upon the nasal septum, but transfers the pressure primarily to softer tissue of the outer nostril walls (Argraves, column 3, line 32). The detailed geometry and the primary benefit of the two inventions are distinguishable as the following discussion will show.

Argraves does in fact disclose a nasal cannula, however primary contact is with the softer tissue of the outer nostril wall (Argraves, column 3, line 32). The items 20/25 referred to in Argraves refer to the support or supply tube and not to the hollow tubular member of

the cannula nosepiece. Argraves does not however teach the geometry of the hollow extensions and the relation of these hollow extension to the geometry of the hollow tubular member. The instant application claim 1 includes "each said hollow extension having a longitudinal axis projecting from said central portion at an ***acute*** [emphasis added] angle from said first plane …" not as the examiner has quoted as an arcuate angle. Figure 3 of Argraves does in fact show arcuate tubular extensions. But arcuate tubular extensions are not part of claim 1. The instant invention also claims the "longitudinal axis projecting from said central portion at an acute angle"… The extensions are not in the same plane as the hollow tubular member. There is no teaching within Argraves of hollow tubular extensions angled away from the central member and in fact a reasonable conclusion from Argraves Figure 3 and the associated discussion is that all of the elements 10, 15, 13 and 17 are in fact in the same plane. The instant application has the tubular extension projecting at an acute angle out of the plane formed by the central hollow tubular member. Examiner is also pointed to Figures 2 and 3 of the instant invention where the tubular extensions 17 and 18 of Figure 3 and therefore the orifice (19 of Figure 2) are at an acute angle from said first plane of the angled central hollow tube member. Further, the hollow extensions terminating in gas directing orifices "… having a longitudinal axis lying in a second plane essentially parallel to and displaced from said first plane…" Again, there is no indication in Argraves Figure 3 or its discussion that the longitudinal axis of elements 13 and 17 are in a plane displaced from and parallel to the plane defined by the central elements 10 and 15. This displaced plane for the terminating orifices is clearly shown in Figure 2 of the instant application element 19.

"Said end portions of said central portion lying in essentially the first plane with the longitudinal axis of said end portion essentially collinear with longitudinal axis of corresponding symmetrical half of said central portion." Argraves Figure 3 however shows that the end portions 10 are in fact arcuate a longitudinal axis would be bent or arcuate and is clearly not collinear with the likewise arcuate axis of the central portion 15.

Applicant therefore respectfully asserts that the elements of claim 1 are not taught by Argrave and that claim 1 should be allowed even in view of Argrave.

Claim 3 also rejected under 35USC 102(b) is dependent upon claim 1. The elements of claim 1 as discussed above are distinguishable from Argraves. Claim 3 is amended with this response to address Examiner's informal objection. In the instant application the orifice are angled in a second plane which is displaced from the first plane that is defined by the hollow central element. There is no indication that elements 13 and 17 of Argraves Figure 3 are in a different plane from elements 10 and 15, let alone a different plane that is displaced from and parallel to the plane formed by elements 10 and 15. Additionally, the orifices of Argrave as shown in Figure 3 elements 13 and 17 are in fact arcuate. The longitudinal axes of the elements are not linear and their intersection in space may in fact be at angle that is greater than 90 degrees thus forming an obtuse rather than acute intersecting angle.

Applicant therefore respectfully assert that claim 3 is also distinguishable from Argraves and should be allowed.

Claim Rejections – 35 USC§103

Claim 2 is rejected under Argraves and the assertion that small orifices are known. However the claim does not refer to an orifice with a diameter of less than .006 inches but rather the "thickness of material forming rim of said orifice is less than .006 inches." The arguments regarding small orifice and drug delivery are not relevant to the instant application or claim. The inventor has found, described and claimed in the instant application that very thin walled material will be deflected by nostril hair rather than act as an irritant. Again the instant geometry as described in independent claim 1 has enabled the use of very pliable material such as the thin orifice material of dependent claim 2. There is nothing in the claim regarding the diameter of the orifice formed using this material.

Claims 4 – 7 and 9 – 13 are rejected as obvious under Argraves in light of Applicant's admission in his response of 7/10/2007. A prima facie case of obviousness may be rebutted evidence or argument to demonstrate that:

> "(A) one of ordinary skill in the art could not have combined the claimed elements by known methods (e.g., due to technological difficulties);

…

or

(C) the results of the claimed combination were unexpected." (MPEP 2141(V))

"…evidence, sometimes referred to as "secondary considerations," may include evidence of commercial success, long-felt but unsolved needs, failure of others, and unexpected results." (MPEP 2141 (II))

One of ordinary skill in the art could not have combined the claimed elements by known methods. Applicant explained in the specification, paragraph 009, and illustrated in Figure 10 that prior art relies upon the stiffness of the tubing to maintain the relative orientation of the cannula to the patient's nose. For this reason one of ordinary skill in the art would not use the tubing described in the instant application for it was known to fail. Applicant provided further evidence of this in the array of patents and applications submitted in the information disclosure statement, none of which teach the use of the tubing of the degree of pliability as claimed in the instant application. Examiner admits that even the cited reference Argraves makes no mention of the particular properties of the tubing. Nor does any of the other references yet uncovered by applicant or examiner. Argraves in fact teaches away from using tubing that is too pliable in pointing out the problem of tubing bending and pinching off the air supply (Argraves column 4 line 62). In fact observing the bending angle required in the Argrave patent, depicted in Figure 1, where supply tubing 25 exits support device 35 at back and Figure 4, bend on right hand side of supply tubing 20, the support and supply tubing of the instant invention would not work with the Argrave design because bent at those angles the tubing would pinch and cut off air supply. Applicant's "admission" of existence of the tubing was made to show that even though the tubing existed, no one of ordinary skill in the art did in fact make use of the tubing. This is because those skilled in the art "knew" the requirement for stiff tubing to maintain the cannula orientation. There is a long-felt need to make use of the claimed tubing that has not been solved as indicated in extensive patent literature and lack of a commercially equivalent product to that offered by the applicant.

Applicant has also offered additional secondary evidence, that of commercial success through customer feedback in the response to the office action of 4/4/2007. The evidence is repeated here for convenience:

> **I have included several customer comments** (found on my website at www.softhose.com) to give an idea of the difference between mine and regular cannulas.
>
> I was so shocked and happy at the difference they make! I can't even begin to tell you the relief I felt, instantly! Thank you so much for making these...
>
> The only thing that has gone right about oxygen for me, so far, had been your cannula. It is so soft, so forgiving, that I truly don't know if it's in place (took a few nighttime wakeups to determine!). Each night when I put it on, I think of my mother and how much she would have liked something so tender on her fragile skin during the last years of her life.
>
> All I can say is WOW! And of course...thank you for developing this wonderful hose! I no longer have 'face dents' or behind the ear irritation and most importantly....the nose piece is SO comfortable! The cannula is so light weight that I hardly know I have one on my face! The hose I purchased from you lays on the floor and I no longer have all that tangled mess in the house and if I happen to step outside for a moment...the hose does NOT get rock hard when it is cold.
>
> Thank you! I am off to order more!
>
> I received your cannula and can say without qualification that it is the BEST! It is super comfortable and, most important of all, it stays put. I have been on oxygen 24/7 for 6 years and have tried them all--there's no comparison. I hope you're gearing up for mass production, because when the growing world of oxygen patients find out about it they will demand it from their oxygen providers, just as they did when Helios was invented. I hope you get your patent quick and corner the market.
>
> I did notice that the softhose cannula has the feel of a rubber band, and as such tends to stay in my nose better than the salter labs cannulas. I have always had a problem of the cannula falling out of my nose when sleeping, and would wake up with air being blown

into my eyes (or my neck). Your cannula tends to stay in my nose while sleeping. This is a MAJOR bonus!

The results of the claimed combination were unexpected. The inventor was employed for many years in the industry designing cannula and related systems. His experience and learning was that soft pliable tubing could not be used. As described in the specification (0036) and Figure 10 prior art cannula in fact use the torsional stiffness of the support tubing to maintain orientation of the cannula in the nostril of the patient. The expectation for the claimed combination is that the cannula would twist and not maintain proper orientation in use if the normal stiff tubing were replaced with the soft, pliable tubing. The expectation of the claimed combination is failure to perform. The fact that cannula have been designed and found that will work with the claimed tubing is unexpected.

New Claims 20 to 24 have been added. These new claims are dependent upon claim 1. The geometry described in claim 1 and discussed at length above enables use of a material for the support tubes with a lower modulus (claim 20), lower hardness (claim 21), less prone to compression set (claim 22) and lower brittle temperature (claim 23). A particular exemplary use of such material is PVC resin containing at least a portion of very high molecular weight material (claim 24). The benefits arise not just from a replacement of the material but also from the geometry that optimizes the benefit of the more flexible lighter supply material. The unique geometric design of the instant application used in combination with the tubing material provides benefits that have previously not been available. The dependent claims 20 – 24 effect the combination of a new unique design with the softer tubing material and clearly are distinguishable from and not an obvious extension of prior art.

In view of the above amendments and remarks, Applicant respectfully submits that all claims are patentable and the entire application is now in condition for allowance.

Respectfully Submitted,

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